K061047

JUN - 8 2006

5.0 510(k) Summary

Submitter:	HemoCue AB Box 1204 Ängelholm, Sweden SE-262 23 +46 431 45 82 00 (Telephone) +46 431 45 82 25 (FAX)
Contact:	Mr. Allan White (Official Correspondent) HemoCue, Inc. 40 Empire Drive Lake Forest, CA 92630-2244 (949) 859-2630 x110 (Telephone) (949) 598-8630 (FAX) allan@hemocue.com
Date of Preparation:	April 13, 2006
Proprietary Name:	HemoCue Hb 301 system
Classification Name:	Automated and Semi-Automated Hematology Devices, Automated hemoglobin system (21 CFR § 864.5620), Product code: GKR
Common Name:	Hemoglobin analyzing system
Equivalent to:	HemoCue AB claims substantial equivalence to the current legally marketed HemoCue Hemoglobin 201 system (K032203)

Description
The HemoCue Hb 301 system consists of a small and portable analyzer (photometer) and plastic microcuvettes. The microcuvette serves both as a pipette and as a measuring cuvette. A blood sample is drawn into the cavity by capillary action. The filled microcuvette is inserted into the HemoCue Hb 301 Analyzer. The measurement takes place in the analyzer, which measures the absorbance of whole blood at a Hb/HbO_2 isobestic point. The system is factory calibrated and needs no further calibration.

Intended use
The HemoCue Hb 301 system is designed for quantitative point-of-care whole blood hemoglobin determination in primary care using a specially designed analyzer, the HemoCue Hb 301 Analyzer, and specially designed microcuvettes, the HemoCue Hb 301 Microcuvettes. The HemoCue Hb 301 system is for In Vitro Diagnostic use only.The HemoCue Hb 301 Analyzer is only to be used with HemoCue Hb 301 Microcuvettes.

Technological Characteristics
The technological characteristics for HemoCue Hb 301 system are equivalent to the predicate devices. The system consists of an analyzer (photometer) together with microcuvettes. The microcuvette is made of polystyrene plastic and contains no active ingredients. The

microcuvette serves both as a pipette and as a measuring cuvette and is for single-use only. A blood sample of approximately 10 µL is drawn into the cavity by capillary action.

The measurement takes place in the analyzer, which measures the absorbance of whole blood at a Hb/HbO2 isobestic point. The analyzer measures at two wavelengths (506 and 880 nm) in order to compensate for turbidity. The HemoCue Hb 301 System is calibrated against the hemiglobincyanide (HiCN) method, the international reference method for the determination of the hemoglobin concentration in blood. The system is factory calibrated and needs no further calibration.

Similarities with predicate device

Claim	**Similarities**
Intended use	Quantitative point-of-care hemoglobin determination in primary care using a specially designed analyzer and specially designed microcuvettes. The HemoCue systems are for In Vitro Diagnostic use only.
Result	Quantitative
Positioning	Point of Care
Analyte	Hemoglobin
Specimen	Whole blood
Labeling	Equal Directions For Use

Assessment of Performance

Studies were conducted in-house, in clinical laboratory settings and point of care centers to demonstrate the performance of the HemoCue Hb 301 system and that the intended user can easily operate the system and obtain results as expected.

Conclusion

The HemoCue Hb 301 system is a convenient method for measuring whole blood hemoglobin and can be used by typical users and provide clinical results comparable to other test methods in current clinical laboratory and point-of-care practices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 8 2006

Mr. Allan White
Official Correspondent
HemoCue, Inc.
40 Empire Drive
Lake Forest, CA 92630-2244

Re: k061047
Trade/Device Name: HemoCue® Hb 301 System
Regulation Number: 21 CFR § 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: II
Product Code: GKR
Dated: April 13, 2006
Received: April 14, 2006

Dear Mr. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

4.0 Statement of Indications of Use

510(k) Number: K061047

Device Name: HemoCue® Hb 301 system

Indications For Use:

The HemoCue Hb 301 system is designed for quantitative point-of-care whole blood hemoglobin determination in primary care using a specially designed analyzer, the HemoCue Hb 301 Analyzer, and specially designed microcuvettes, the HemoCue Hb 301 Microcuvettes. The HemoCue Hb 301 system is for In Vitro Diagnostic use only. The HemoCue Hb 301 Analyzer is only to be used with HemoCue Hb 301 Microcuvettes.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061047